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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,710	10/31/2001	Shlomo Ben-Haim	20066-86	3830

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REED SMITH, LLP
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599 LEXINGTON AVENUE, 29TH FLOOR
NEW YORK, NY 10022-7650

EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/001,710

Applicant(s)

BEN-HAIM ET AL.

Examiner

Carl H. Layno
4/13/05

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 10, 16 and 17 is/are allowed.
- 6) ☒ Claim(s) 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on March 15, 2005 has been entered.

2. Claims 1-8 are canceled. Claims 9-17 are active and pending.

Priority

3. Acknowledgment is made of applicant's claims for priority based upon previously filed U.S. Provisional Applications. For the purposes of this examination, the priority filing date of 2/5/96 is used since this application is the first to disclose an "electrical muscle controller" utilizing applicant's currently claimed "non-excitatory" signals. Although the applicant also cited U.S. Provisional Application 60/009,769 (filed 1/11/96), this application made no mention of applying "non-excitatory" signals to the patient.

Information Disclosure Statement

Art Unit: 3762

4. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449) which was received by the Office on March 22, 2005. This document is the third copy received of Applicant's "Third Supplemental Information Disclosure Statement". Copies of each cited reference were delivered by messenger and personally received by the Examiner in mid-March 2005.

Drawings

5. Applicant's formal drawings were received by the Office on October 31, 2001 and have been approved by the Examiner.

Claim Rejections - 35 USC § 102

6. The indicated allowability of claims 11-15 are withdrawn in view of the newly discovered reference(s) to Fromer et al and Scherlag. Rejections based on the newly cited reference(s) follow.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by the Fromer et al article: "Ultrarapid Subthreshold Stimulation for Termination of Atrioventricular Node Reentrant Tachycardia" (JACC, Vol.20, No.4, October 1992: 879-883) (Applicant's cited prior art).

The article by Fromer et al entitled: "Ultrarapid Subthreshold Stimulation for Termination of Atrioventricular Node Reentrant Tachycardia" (JACC, Vol.20, No.4, October 1992: 879-883), which was cited by the Applicant as prior art, describes an apparatus and method for treating AV node reentrant tachycardias and preventing atrial fibrillations by applying ultra-rapid sub-threshold electrical stimulation to parts of the right atrium and coronary sinus. The applied electrical stimulation comprised trains of low powered pulses having insufficient strength to cause atrial capture (Abstract – "Results" section). The pulses were applied through a distal pair of electrodes (p.879, right column, "Methods", lines 19-20) located on the right atrium and proximal coronary sinus (p.880, left column, 2nd paragraph).

9. Claims 13-15 were also rejected under 35 U.S.C. 102(b) as being anticipated by Scherlag '564 (Applicant's cited prior art).

The Scherlag '564 patent, cited by the applicant as prior art, describes a method and apparatus for alleviating and diagnosing symptoms of heart block involving the delivery of sub-threshold electrical stimulations to the heart (Abstract). Although the Examiner mentioned reasons why a similar reference (i.e. Scherlag '642) was inapplicable in a previous office action dated 5/27/04, the Scherlag '564 patent discloses an embodiment (col.2, lines 51-55) in which sub-threshold stimuli are applied to the AV junction in the heart to induce heart block symptoms (i.e. inhibit propagating action potentials) as part of a heart block diagnosis methodology.

In regard to claim 14, the stimulation signals generated by stimulus generator 12 (Fig.1) would inherently create their own electric field.

In regard to claim 15, the Scherlag '564 apparatus is equipped with a stimulation lead having 2-4 electrodes (Figs.1-3B).

Allowable Subject Matter

10. Claims 9, 10, 16, and 17 are allowed.

Reasons for Allowance

11. The following is an examiner's statement of reasons for allowance:

Claims 9, 10, 16, and 17 are still deemed to be allowable over the prior art of record since they disclose methods and apparatus, respectively, pertaining to the use of "non-excitatory stimulus" signals to a patient's heart or "portion thereof" as a precursor to cardiac surgery. Of the prior art references disclosed by the Applicant, only the Matheny et al '378 and Taylor et al '876 patents disclose devices which slow a patient's heart rate for surgical reasons. Unlike applicant's claims, however, Matheny et al '378 discloses a method involving the application of stimulation pulses to the patient's vagal nerve, not to the patient's heart, to reduce heart activity. Similarly, Taylor et al '876 discloses a vagal nerve stimulator, however unlike Matheny et al, Taylor et al shows that one of its stimulation electrodes (Fig.22) appears to be located on the patient's heart (Clip Position #4). This reference, however, could not be used by the Examiner because of its defective pertinent filing date (7/3/1997). Other pertinent references cited by the Applicant making use of sub-threshold cardiac stimulation signals were Mower '351 and Kieval '464. Mower discloses a multi-site device used in atrial defibrillation while Kieval discloses a system for enhancing cardiac function. Both references fail to teach applicant's claimed use of

Art Unit: 3762

inhibiting heart activity for surgical purposes, and are also deficient with respect to priority filing dates.

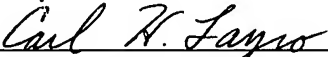
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (571) 272-4955. All faxed correspondence should be sent to the Office's Official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (571) 272-4399.



CARL LAYNO
PRIMARY EXAMINER

CHL
04/13/2005